IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
Fort Worth Division

OUTSOURCING FACILITIES ASSOCIATION, et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, et al., Defendants.	Civil Action No. 4:24-cv-00953-P

[Proposed] Order Granting Motion For Preliminary Injunction

This case comes before the Court on the motion of Plaintiffs Outsourcing Facilities Association ("OFA") and North American Custom Laboratories, LLC, doing business as FarmaKeio Custom Compounding ("FarmaKeio"), for a preliminary injunction prohibiting the Food and Drug Administration ("FDA") from taking action against OFA members and FarmaKeio based on their compounding of the drug ingredient Tirzepatide pending final judgment in this case.

Finding good cause for the motion, the Court **GRANTS** the motion on the terms stated below. The Court states the good cause supporting this order as follows:

A plaintiff seeking a preliminary injunction "must establish (1) a likelihood of success on the merits; (2) a substantial threat of irreparable injury; (3) that the threatened injury if the injunction is denied outweighs any harm that will result if the injunction is granted; and (4) that the grant of an injunction will not disserve the public interest." *Ladd v. Livingston*, 777 F.3d 286, 288 (5th Cir. 2015) (quoting *Trottie v. Livingston*, 766 F.3d 450, 452 (5th Cir. 2014)). "Preliminary injunctions commonly favor the status quo and seek to maintain things in their initial condition so far as possible until after a full hearing permits final relief to be fashioned." *Wenner v. Tex. Lottery Comm'n*, 123 F.3d 321, 326 (5th Cir. 1997). In this case, Plaintiffs have established these elements,

and an injunction is proper to prevent irreparable harm and preserve the status quo until final judgment can be rendered in this case.

1. Plaintiffs have a substantial likelihood of success on the merits. FDA removed Tirzepatide from the shortage list (the "Delisting Action") without notice-and-comment rulemaking required by the Administrative Procedure Act ("APA"). *See* 5 U.S.C. § 553(c); *U.S. Dep't of Labor v. Kast Metals Corp*., 744 F.2d 1145, 1153 n.17 (5th Cir. 1984). The Delisting Action is clearly an agency "rule," because it qualifies as "the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy." 5 U.S.C. § 551(4); *see Apter v. Dep't of Health & Hum. Servs.*, 80 F.4th 579, 590 (5th Cir. 2023) (explaining that this definition reaches "virtually every statement an agency may make"). And the Delisting Action is a substantive rule because it has "the force and effect of law." *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 103 (2015). When FDA removes a drug from the shortage list, permissions under the Food, Drug, and Cosmetic Act ("FCDA") for compounding from bulk substances of the drug (Section 503B) or compounding copies of the drug (Section 503A) are eliminated, which renders formerly lawful activity unlawful. For that reason, the Delisting Action is not exempt from notice-and-comment process as agency guidance or internal-process directives. Nor does anything in the FDCA exempt FDA from notice-and-comment rulemaking when it undertakes relevant actions.

Separately, Plaintiffs are likely to prevail because of FDA's lack of reasoned decisionmaking. Whether or not notice-and-comment rulemaking is mandated, an agency must justify its final action with a "reasoned analysis." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983). Provisional relief is warranted where no reasoned analysis accompanies final agency action. *Ohio v. EPA*, 144 S. Ct. 2040, 2054 (2024). Here, FDA failed to provide "a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *State Farm*, 463 U.S. at 43 (citation omitted). FDA has "barely articulated any basis at all" for the Delisting Action, *BNSF Ry. Co. v. Fed. R.R. Admin.*, 62 F.4th 905, 911 (5th Cir. 2023), noting only that "FDA confirmed with the

drug's manufacturer that their stated product availability and manufacturing capacity can meet the present and projected national demand."

This does not address many obvious questions, including what information FDA received from the manufacture, what FDA did to evaluate that information, why FDA deemed the "stated" capacity, supply, and demand so credible as to be dispositive, and what FDA did to account for inherent self-interest of the manufacturer in the decision. Moreover, FDA's statement falls well short of explaining to the public what FDA believes the demand and projected demand of the drug to be what it believes the existing supply to be, or its bases for either determination. Importantly, the Delisting Action does not explain how FDA determined (or whether it determined) that the manufacture's supply of Tirzepetide can meet demand satisfied since December 2022 by lawful compounding. Additionally, the administrative record—if properly compiled—is likely to show that FDA received information strongly indicating a continuing shortage of Tirzepatide, but FDA's action fails even to mention (let alone respond to) this information. Whether or not FDA has answers to these questions is beside the point: it should have addressed the factors *in its rulemaking*. Anything it might say in litigation will come too late. *Dep't of Homeland Sec. v. Regents of the Univ. of California*, 140 S. Ct. 1891, 1909 (2020). For that reason, it is hard to see how FDA can persuasively counter a preliminary injunction motion, and this justifies interim relief pending resolution of that motion.

Moreover, "[i]llogical and internal inconsistency are characteristic of arbitrary and unreasonable agency action." *Chamber of Com. of United States of Am. v. United States Dep't of Lab.*, 885 F.3d 360, 382 (5th Cir. 2018). The Delisting Action is illogical and internally inconsistent in that all its factual assertions—including predictions of "intermittent localized supply disruptions" and warnings that "Patients May Not Always Be Able To Immediately Fill Their Prescription"—suggest an ongoing shortage. The point of maintaining a shortage list is for FDA to ascertain whether supply can satisfy demand. Findings that supply will not satisfy demand are an illogical and inconsistent basis for a declaration that a shortage has ended.

For all these reasons, Plaintiffs are likely to succeed in establishing APA violations on the merits. This factor favors a temporary injunction to preserve the status quo.

2. All equitable factors also favor an injunction. Absent immediate relief, FarmaKeio and OFA members will be irreparably harmed. *See, e.g.*, *Wages & White Lion Invs., LLC v. United States Food & Drug Admin.*, 16 F.4th 1130, 1142 (5th Cir. 2021) (holding that plaintiff proved irreparable harm based on FDA's action forbidding its product manufacturing and marketing). They will suffer financial loses that "cannot be undone through monetary remedies," *Interox Am. v. PPG Indus., Inc.*, 736 F.2d 194, 202 (5th Cir. 1984), given that sovereign immunity forecloses any monetary recovery in this case, *Wages & White Lion*, 16 F.4th at 1142.

The balance of harms and public interest also favor an injunction. These factors "'merge when the Government is the opposing party,'" *Texas v. Becerra*, 577 F. Supp. 3d 527, 561 (N.D. Tex. 2021) (quoting *Nken v. Holder*, 556 U.S. 418, 435 (2009)), and they favor an injunction. The public has a substantial interest in continued access to compounded Tirzepatide at least until the Court decides the pending preliminary-injunction motion. The public also has a "substantial public interest in having governmental agencies abide by the federal laws that govern their existence and operations." *Texas v. United States*, 40 F.4th 205, 229 (5th Cir. 2022). It is "not in the public interest to suspend notice and comment. Notice and comment are not mere formalities. They are basic to our system of administrative law." *Nat. Res. Def. Council v. Nat'l Highway Traffic Safety Admin.*, 894 F.3d 95, 115 (2d Cir. 2018).

A preliminary injunction will impose no cognizable harms. FDA cannot plausibly claim injury from following congressional dictates and making a reasonably informed—rather than arbitrary—decision. Nor can FDA claim cognizable harm from a 14-day continuation of compounding that was lawful in FDA's own view until a few days ago and had been continuously meeting public demand and patient needs since December 2022. FDA's basis for declaring the shortage over was unrelated to public health or safety, and maintaining an effective state of shortage does nothing to prevent FDA from enforcing the many mechanisms of the FDCA designed to protect public safety. *See, e.g.*, 21 U.S.C. § 353b(b)(1) and (2) (registration, inspection,

and reporting requirements); *id.* § 353b(a)(4) (FDA prerogative to forbid outsourcing-facility compounding where "drugs or components of such drugs have been found to be unsafe or not effective"); *id.* § 353a(b)(1) (quality standards); *id.* § 353a(b)(3) (FDA prerogative to forbid pharmacy compounding of drug "that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product").

Thus, the balance of equities favors a temporary restraining order to prevent irreparable harm and serve the public interest pending fulsome briefing and adjudication of the pending preliminary-injunction motion.

3. No security is necessary to support a preliminary injunction under Federal Rule of Civil Procedure 65(c). The amount of security required "is a matter for the discretion of the trial court," and the Fifth Circuit has held district courts have discretion to "require no security at all." *Kaepa, Inc. v. Achilles Corp.*, 76 F.3d 624, 628 (5th Cir. 1996) (citing *Corrigan Dispatch Company v. Casa Guzman*, 569 F.2d 300, 303 (5th Cir. 1978)). FDA will not suffer financial harm from an injunction that would make a security requirement proper, so the Court exercises its discretion to require no security.

For the foregoing reasons, the Court **GRANTS** Plaintiffs' motion for a preliminary injunction and **ENJOINS** for the pendency of this action or until further order of this Court the Food and Drug Administration from taking action against Plaintiffs for engaging in compounding of Tirzepatide that is lawful in circumstances where Tirzepatide is named on the drug-shortage list so long as that compounding complies with conditions applicable in circumstances where Tirzepatide is named on the drug-shortage list.

IT IS SO ORDERED.

Dated: _____

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United States District Judge